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EXAMINER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 24

Application Number: 09/456,110
Filing Date: December 07, 1999
Appellant(s): LUO ET AL.

Khaled Shami
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/31/02.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The rejection of claims 1-3 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(9) Prior Art of Record

3,425,419	DATO	4-1969
5,486,208	GINSBURG	1-1996
6,254,626 B1	DOBAK et al.	7-2001
6,090,132	FOX	7-2000

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over DATO (U. S. Patent No. 3,425,419) or GINSBURG (U. S. Patent No. 5,486,208) in view of DOBAK (U. S. Patent No. 6,254,626) and FOX (U. S. Patent No. 6,090,132). Dato and Ginsburg each disclose a method of advancing a heat exchanger into a central venous vein of a patient for hypothermia treatment (2:40-52 and 4:20-23 respectively). Although Dato and Ginsburg disclose the advantages of inducing hypothermia neither specifically address using the method in a stroke patient for treatment nor monitoring and maintaining blood pressure during the procedure. Fox discloses that hypothermia is the most effective known therapy for stroke (1:20-33). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the step of identifying stroke patients as taught by Fox with the method of inducing hypothermia as disclosed by Dato or Ginsburg in order to accomplish a well known effective treatment for stroke patients. Dobak teaches that blood pressure is maintained during hypothermia treatment (col. 2, lines 29-40). It would have been obvious to one of ordinary skill in the art at the time of the invention monitor and maintain blood pressure as taught by Dobak in the method of Dato or Ginsburg and Fox to effectively and safely perform the surgical procedure.

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(11) Response to Argument

Applicant argues that there is no motivation to combine the cooling teachings of Fox with the cooling teachings of Dato because Fox teaches away from the cooling teachings of Dato.

The examiner maintains that a prima facie case of obviousness is established in view of the prior art of record. A prima facie case of obviousness is established when, inter alia, “some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). “The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved.” Kotzab, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). With respect to establishing a prima facie case of obviousness by combining the teachings of Dato and Fox, the motivation to combine the teachings is found in statements in the prior art references as well as in the knowledge generally available to one of ordinary skill in the art.

The Fox and Dato references are concerned with inducing hypothermia in a patient for medical purposes. Fox discloses a method of cooling whereby a patient’s hypothalamus gland is heated to trick the body into cooling itself using normal physiological mechanisms. Dato relies on a method of cooling involving advancing an indwelling heat exchange catheter into a central venous vein of a patient and circulating cooling fluid (col. 2, lines 47-53; col. 3, line 45 - col. 4, line 15).

Dato teaches a preferred embodiment using hypothermia in open heart surgery, but recognizes that hypothermia may be desired for other reasons where one of ordinary skill in the

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art desires to obtain cooling “in cases of intractable hypothermia.” (col. 5, lines 36-40). Dato points out that his method of cooling is particularly valuable when a quick or rapid cooling is needed (col. 1, lines 36-43; col. 2, lines 14-18).

Fox states that it is known by practitioners in the fields of treating stroke and head trauma that “one of the most effective therapies known for these and similar conditions is hypothermia, the lowering of the body temperature.” Furthermore, Fox acknowledges it is general knowledge in the art that hypothermia treatment achieved soon after initial injury helps improve neurological outcome (col. 1, lines 20-45). It is clear that one of ordinary skill in the art of stroke treatment would recognize that a method of inducing hypothermia quickly after stroke would result in an effective treatment, reducing neurological damage. Knowing Dato’s method using a heat exchange catheter in a central venous vein to achieve rapid hypothermia, it would have been obvious to the skilled artisan at the time of the invention, in view of Fox’s disclosure of the knowledge generally available to those of ordinary skill in the art of treating stroke, to use Dato’s method for treatment of stroke victims.

Applicant argues that Fox teaches away from the method disclosed by Dato because Fox does not directly cool the body (i.e., avoids dealing with a body’s own resistance to cooling). The examiner maintains that Fox, viewed in its totality, would lead one of ordinary skill in the art to modify the method of Dato to treat stroke victims, not discourage one from doing so.

Fox lists various hypothermia methods that he views as impractical and risky. However, Fox does not include the method disclosed by Dato (i.e., advancing a heat exchange catheter into a patient’s central venous vein to induce hypothermia) as one of these methods to avoid. Fox may teach away from some hypothermia methods (col. 1, line 66 - col. 2, line 57), but there is no

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teaching by Fox to avoid the method disclosed by Dato. At the most Fox discloses his method as “ideal” because it uses a body’s own physiological temperature control mechanisms, not opposes them (col. 2, lines 53-57).

One of ordinary skill in the art would recognize that the “ideal” method of Fox can not always be relied upon and a different hypothermia method could be required to treat stroke. Fox discloses utilizing a patient’s hypothalamus to regulate body temperature to effect a cooling response (col. 3, lines 33-45) after a stroke. However, Fox also points out that stroke victims suffer some degree of neurological damage (col. 1, lines 21-24). The skilled artisan would also recognize that brain function may be impaired after a stroke, and that normal physiological responses may not occur after such damage. If the embolic element blocked blood flow to the hypothalamus, its function could be impaired and it would not be prudent to solely rely on its normal functioning for treatment, especially when time is important. This would be knowledge generally available to one of ordinary skill in the art (i.e., a medical practitioner). Because an artisan must be presumed to know something about the art apart from what the references disclose, see In re Jacoby, 135 USPQ 317, 319 (CCPA 1962), it must be recognized that a medical practitioner may need to search for another method of rapidly cooling a patient’s body after a stroke, especially if the hypothermia treatment is difficult to manage due to an impaired hypothalamus. One of ordinary skill in the art, knowing the teachings of Dato, would find it obvious to modify the rapid cooling method of Dato to use it to treat stroke patients. One of ordinary skill in the art would use the method disclosed by Dato to achieve a rapid, non-physiological method of inducing hypothermia to treat stroke motivated by the knowledge that a

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fast cooling treatment is desirable to treat stroke and an “ideal” hypothermia disclosed by Fox may not be successful when needed.

Applicant argues that there is no motivation to combine Ginsburg and Fox because Ginsburg teaches cooling a body using a catheter system while Fox discloses cooling by heating the hypothalamus.

Ginsburg discloses a method of inducing artificial hypothermia in a patient when medically necessary by advancing a heat exchange catheter into a central venous vein and circulating cooling fluid (col. 4, lines 17-56; col. 5, lines 49-56). Ginsburg does not disclose use of his cooling method during stroke. Fox states that inducing hypothermia to treat stroke is well known treatment to reduce neurological damage (See above).

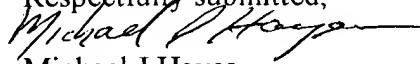
The arguments applied above with respect to combining the teachings of Dato and Fox are also applicable to the finding of motivation to combine the teachings of Ginsburg and Fox. The examiner maintains that there is motivation to combine the teachings of Ginsburg and Fox and such motivation is found in the prior art references and in the knowledge generally available to one of ordinary skill in the art (See discussion above). Ginsburg states that his disclosed method of inducing cooling quickly achieves hypothermia (col. 3, lines 11-20). Fox states that hypothermia is known as an effective stroke treatment and that time to achieving hypothermia after a stroke occurs is important to successful treatment of stroke victims (See above). These disclosures, in view of the knowledge of the skilled artisan that the hypothalamus may not be functioning normally after stroke, would motivate one of ordinary skill in the art to combine the

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teachings and knowledge disclosed in the references to arrive at the claimed invention to provide an effective therapy for stroke victims.



With regard to claims 2 and 3 Dobak discloses that it is known in the art to monitor and maintain blood pressure during hypothermia treatment (col. 2, lines 29-40). Knowing that blood pressure is a parameter that is important for judging a patient's health while performing a surgical procedure or procedure that affects physiological functions, it would have been obvious to one of ordinary skill in the art to combine Dobak with the prior art of Dato and Fox or Ginsburg and Fox to perform a safe treatment for stroke.

Applicant gives arguments against a combination of the teachings of Dobak and Dato as well as Dobak and Fox with respect to using a heat exchange catheter advanced into a patient's venous vein to treat stroke via hypothermia. Since the rejection clearly used Dobak solely for showing that it is well known in the art to monitor and maintain blood pressure during hypothermia treatment, the examiners comments with respect to Dobak are limited to this issue. For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Michael J Hayes
Primary Examiner
Art Unit 3763

mjh
March 13, 2003

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